

REMARKS

Claims 1 and 30-54 were pending in this application. The Examiner has withdrawn claims 30-54 from consideration. Claim 1 has been amended to recite a recombinant influenza virus the genome of which contains a region encoding a tumor antigen wherein the tumor antigen is a breast carcinoma antigen. New claim 55, which claims the recombinant influenza virus of claim 1 wherein said breast carcinoma antigen is HER-2, has been added to clarify what Applicants regard as the invention. New claim 55 is fully supported by the specification of the present application and does not constitute new subject matter. Support for amended claim 1 and new claim 55 can be found, e.g., at page 3, lines 12-25; page 8, Table 1; page 8, line 31 to page 9, line 31; page 10, lines 14-17; page 17, lines 1-36, and page 19, line 18 to page 20, line 25 of the specification. Upon entry of these amendments, claims 1 and 55 will be pending in this application.

Applicants respectfully request entry and consideration of the foregoing amendments and remarks.

REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, SHOULD BE WITHDRAWN

For claim 1, the Examiner contends that the specification allegedly does not contain sufficient written description to enable the full scope of the invention as claimed. As Applicants discuss below, and as further validated by the Declaration of Dr. Adolfo Garcia-Sastre presented previously under 37 C.F.R. §1.132 (hereinafter "Garcia-Sastre Declaration"), amended claim 1 and new claim 55 are enabled by the specification as filed, and the rejection of these claims should not be maintained.

The Examiner acknowledges the Garcia-Sastre Declaration but argues that the construction of a recombinant influenza virus expressing the HER-2 E75 epitope does not correspond with the claimed influenza virus expressing any tumor-associated antigen ("TAA"). Applicants submit that, following the amendment of claim 1 and the addition of claim 55, and as further evidenced by the Garcia-Sastre Declaration, the instant specification provides an enabling disclosure to construct and use recombinant influenza viruses containing breast carcinoma antigens.

As discussed in the previous response, the Garcia-Sastre Declaration details how, using methods described in the specification of the instant application, a recombinant influenza virus may be constructed to express a tumor-associated antigen identified in the

instant application, the HER-2/neu breast carcinoma tumor associated antigen, E75¹, and assayed to determine the ability of said virus to stimulate an immune response (*see* the Garcia-Sastre Declaration at ¶¶ 4-5). This recombinant influenza virus expressing a tumor antigen within the influenza nonstructural (NS) region ("KIF-NS containing E75 virus") was successfully engineered using techniques described in the specification of the instant application.

CONCLUSION

Applicants respectfully request entry and consideration of the foregoing remarks. The full scope of the pending claims are believed to be enabled by the instant specification and patentable. Withdrawal of all the rejections and objections and an allowance are earnestly sought.

If any issues remain, the Examiner is requested to telephone the undersigned.

Date: May 17, 2004

Respectfully submitted,

by *Jacqueline Bena*
Reg No. 48,492

Laura A. Coruzzi 30,742
Laura A. Coruzzi (Reg. No.)
JONES DAY
1155 Avenue of the Americas
New York, New York 10036-2711
(212) 790-9090

Enclosures

¹ The HER-2/neu antigen is identified as an example of a tumor-associated antigen in the instant specification at p. 8, Table 1, under the heading "Non-melanoma antigens".